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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant : William J. Schmidt
Serial No. : 09/385,405
Filed : August 30, 1999
For : METHOD FOR THE PURIFICATION AND
RECOVERY OF WASTE GELATIN
Examiner : R. J. Popovics
Art Unit : 1723
Attorney Docket No. : 671.1.002 CIP-3

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Commissioner for Patents
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RESPONSE TO FINAL OFFICE ACTION

Dear Sir:

This is in response to the final Office Action of May 21, 2002. Claims 71 - 83
stand rejected under 35 U.S.C. Section 112 on the ground that the claims contain
5 language which is unsupported by the originally filed specification. In particular, an
objection is lodged against the phrase "said waste material containing at least one first
component which cannot effectively be separated from the first liquid into a non-solvent
based layer". A further objection is lodged against claim 72 for employing the phrase

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"the first component is selected from oily-type materials, particulates in combinations thereof having an affinity for the solvent". The rejection is hereby traversed and reconsideration is respectfully requested.

Generic claim 71 is directed to a method of treating a waste material containing
5 gelatin. The waste material is obtained from manufacturing and production processes as described in the paragraph bridging pages 1 and 2 of the specification. As indicated beginning at page 2, line 6 a certain amount of the encapsulating material (gelatin) and the encapsulated material (e.g. oil) is lost as waste. It is well known in the prior art to try to recover gelatin and purify it as indicated at page 2, lines 16-17.

10 The waste material of encapsulation processes is comprised of a variable number and types of components (e.g. water soluble and water insoluble) added to a gelatin base (page 2, lines 19-20). These components include solvents (usually water); softening agents and oil coatings (when desired); and residual active ingredients (page 2, line 20 to page 3, line 2). Additional components include colorings and preservatives
15 (page 3, line 3). As used herein as well as in the specification, when such components are present in the waste material and therefore need to be removed, they may be referred to as contaminant.

The object of a successful recycling process involves not only the recovery of gelatin, but also the removal of the remaining components of the waste in order to
20 achieve a relatively pure, reusable product (page 3, lines 3-6).

One of the advantages of a preferred form of the present invention as indicated at page 5, beginning at line 3 is to provide a method for recycling gelatin containing encapsulation waste materials that recycles gelatin and glycerin in situ. The clear meaning of "in situ" is that the process is carried out in a single operation without the need for any additional processing. One of ordinary skill in the art would know the meaning of this term and would understand the present invention in that context.

Referring now to claim 71 of the present application, step (a) combines the waste material (which contains gelatin) and a solvent for the gelatin (e.g. typically water) to form a first liquid containing gelatin. Step (a) then states that the waste material contains at least one first component which cannot effectively be separated from the first liquid into a non-solvent based layer. The Office Action contends that this recitation is unsupported by the originally filed application. This ground of rejection is unfounded and is respectfully traversed.

The purpose of this language is to make it clear that the claimed process is directed towards the treatment and removal of contaminants contained within the solvent based layer formed after the solvent is added. These contaminants are identified as first components in claim 71. When the first liquid is separated into a solvent based layer and a non-solvent based layer, the first components remain in the solvent based layer (e.g. because they are readily dissolved therein) or otherwise have an affinity for the solvent based layer. Thus, step (a) of the present invention defines the waste material as containing a contaminant (i.e. at least one first component) which

does not reside in the non-solvent based layer, but rather has an affinity for the solvent based layer such as being dissolved therein.

Step (b) of original claim 1 stated "separating the liquid (obtained from step (a)) into a solvent based layer and a non-solvent based layer and step (c) of original claim 1 stated "removing residual oils and/or particulates from the solvent based layer to form a second liquid containing gelatin having a higher purity than the first liquid".

Thus, from the beginning of prosecution of the present application, the claims filed in connection with the present invention has been directed to first separating the liquid into a solvent based layer and a non-solvent based layer and then treating the solvent based layer to remove contaminants contained therein.

The phrase which has been objected to in the present Office Action merely indicates that there is a contaminant (at least one first component) that ends up in the solvent based layer. Indeed, the purpose of adding a solvent for the gelatin in step (a) is to provide a two phase system. The two phases are in the form of a solvent based layer containing gelatin and a non-solvent based layer which does not contain meaningful amounts of gelatin. As previously indicated, the waste material may contain a variety of different components in addition to gelatin. Some of these components may have an affinity for the solvent based layer while others do not. The components which have an affinity for the solvent based layer (e.g. are at least significantly soluble in the solvent) remain with the solvent based layer while the components which do not have an affinity for the solvent based layer (e.g. are not soluble in the solvent) will gravitate

towards the non-solvent based layer. This is the entire purpose of forming a two layer system and then separating the two layers into a solvent based layer and a non-solvent based layer.

5 The statement in the Office Action that the recitation is unsupported in the originally filed specification is clearly erroneous. The entire purpose of the present invention is to provide the separation of two layers and to focus on removing contaminants from the solvent based layer which contains the gelatin. As will be discussed in more detail below, the Schmidt patent cited herein as the primary reference concerns itself with removing contaminants from the non-solvent based layer
10 while the present invention clearly is concerned with treating the solvent based layer to remove contaminants which have an affinity for this phase of the system.

In addition to the support provided by the original claims, page 13 of the specification, (lines 11-13) states that if the separated aqueous layer (i.e. the solvent based layer obtained after step (b) of claim 71) contains particulates and/or oily type
15 materials (i.e. materials which have an affinity for the solvent based layer and which are referred to in step (c) of claim 71 as "the first component") then the solvent based layer is treated by a number of different processes specifically supported in the specification following the above-mentioned description on page 13.

20 In the Office Action, the Examiner seems confused as to why the expression "If" is used (see the top portion of page 4 of the Office Action). As previously indicated, the waste material intended for treatment from a gelatin encapsulation process may contain

a variety of contaminants. If none of the contaminants find its way into the solvent based layer, then there is no need to practice the present invention because the solvent based layer can be treated in a manner described in the Schmidt et al. reference to provide a purified recyclable gelatin stream. The present invention, to the contrary, is specifically directed to gelatin waste material which contains at least one first component which finds its way into the solvent based layer because it has an affinity for the same along with the gelatin. This solvent based contaminant (i.e. first component) must be removed and the present process provides a novel and unobvious means for doing so.

Step (a) of claim 71 specifically states that the waste material contains at least one first component which cannot effectively be separated from the first liquid into a non-solvent based layer. This means that that first component (at least one of which must be present) finds its way into the solvent based layer and is thus treated in accordance with the present invention. Thus, any assertion that claim 71 is unclear on this basis is without merit and is entirely unfounded.

Claim 72 states that the first component is selected from oily type materials, particulates and combinations thereof having "an affinity for the solvent". This claim is objected to as introducing new matter. This ground of rejection is hereby traversed and reconsideration is respectfully requested.

As previously explained, adding a solvent to the waste material "for the gelatin" means that the solvent will dissolve the gelatin. Other components contained within the

waste material will either have an affinity for the solvent or they will not. For example, when water is used as the solvent (the most common solvent) components contained within the waste-material will have an affinity for the solvent if they, for example, are at least substantially dissolved or emulsified in water. The term "affinity" as used in the present application is clearly used for its common meaning and is not employed in any technical scientific sense. The word "affinity" simply means that a component will preferentially become part of one layer over another. For example, when the solvent based layer and the non-solvent based layer are in proximity to each other a component having an affinity for the solvent based layer will preferentially become associated with the solvent based layer as opposed to the non-solvent based layer such as by becoming dissolved or emulsified therein. Components which do not have an affinity for the solvent will of course not be associated with the solvent based layer and therefore have an affinity for the non-solvent based layer. Thus, one of ordinary skill in the art would know and readily understand the expression "an affinity for the solvent" and the same does not therefore raise a new matter issue when viewed in the context of the present application and the claims which have been on record from the original filing of the application.

Furthermore, one of reasonably skill in the art to which the present invention is directed would readily know which components (contaminants) have an affinity for the solvent based layer since the solvent of the present invention (e.g. water) is an integral part of the capsule forming process.

Before proceeding with further comments regarding the Office Action, an additional comment regarding encapsulation processes and specifically the recovery of waste gelatin in connection therewith is worthy of note. While it is clear that the desirable goal of any waste gelatin recovery process is to provide 100% pure gelatin, no single commercially viable process is likely to achieve the 100% goal. Accordingly, the separation and removal of components which may be viewed as contaminants is not 100% perfect and trace amounts of such contaminants may appear in the final product. Fortunately, such recovered products can be used for encapsulation because the presence of trace amounts of contaminants does not adversely affect capsules which are formed from the recycled gelatin.

In this context, paragraph 5 of the Office Action states that it is unclear what is meant by "effectively". The term "effectively" appears in step (a) of claim 71 wherein it is stated that the at least one first component can not effectively be separated from the first liquid into a non-solvent based layer. In the context of the present invention and as would be apparent to any one of ordinary skill in the art, the clear meaning of the term "effectively" is to indicate that the present process is applicable to those waste streams in which there is an amount of at least one first component (contaminant) in the solvent based layer sufficient to adversely affect the recycled gelatin. If the solvent based layer contains nothing more than a trace amount of a first component and that amount does not adversely affect use of the recycled gelatin containing the same for encapsulation, then there is no reason to employ the present invention for removing the first component. The type of waste stream that is treated in accordance with the present invention is one containing at least one first component which is present in an

amount which can adversely affect the recovered gelatin product. This concept is not only supported in the application as filed but is clearly logical to anyone having any experience in the art to which the present application contains.

Paragraph 5 of the Office Action states that it is unclear why this "first component
5 can not be effectively separated". Such first components can not be effectively separated because, for example, they do not have an affinity for the solvent (e.g. are not readily dissolved in or emulsified by the solvent) chosen to dissolve the gelatin. Since some first components have an affinity for the solvent (e.g. are readily dissolved in or emulsified by the solvent) they end up in that layer. The reason why some
10 components end up in the non-solvent based layer goes back to basic chemistry, e.g. some materials dissolve in the solvent and others do not.

Paragraph 6 of the present Office Action raises an issue as to the meaning of "in situ" and that because there is no mention of "in situ" in the claims the present invention does not distinguish over Schmidt et al. (U.S. Patent No. 5,288,408). As will become
15 apparent from the discussion below in dealing with the prior art of record, the claims of the present application clearly distinguish over the invention taught in Schmidt et al. and there is no reason or necessity for inserting the words "in situ" in the present claims to distinguish over the prior art of record.

Thus, it is clear that the claims of the application are supported in the application
20 and completely and properly express the essential features of Applicant's process in a manner which would be understood by those of ordinary skill in the art.

Claim 71-83 stand rejected as anticipated by Schmidt et al. (U.S. Patent No. 5,288,408). The same claims have been rejected over the same reference on obviousness grounds under 35 U.S.C. Section 103(a). In support of this rejection, page 9 of the Office Action states that column 4, line 22 of Schmidt et al. indicates that the solvent based layer is filtered to remove "any remaining traces of oil or other contaminants". As indicated in the Office Action, the only oil or other contaminants referred to in the '408 Patent specification are those that reside in the non-solvent based layer. Thus, Schmidt et al. uses certain types of filter equipment to remove the last remaining traces of contaminants that spilled over from the sight glass separation process of step (b) so that the filtrate containing gelatin and glycerin is not contaminated with these non-solvent based contaminants. The rejection is hereby traversed and reconsideration is respectfully requested.

Column 3, line 64 of Schmidt et al. shows that once gelatin is completely dissolved in the solvent there follows the separation of the lower aqueous phase (solvent based layer) from the upper oil phase (non-solvent based layer) by a sight glass incorporated into the recycling process. It is well known in the art that separation by sight glass does not provide a complete separation of the two layers. A very minor amount (e.g trace amount) of the non-solvent based contaminants will spill over into the solvent based layer. It is a very small amount of non-solvent based contaminants which is the subject of the next portion of the Schmidt et al. patent reference.

As indicated at column 4, beginning at line 9 the upper phase contains the lubricating or coating oils, active ingredients, coloring and preservatives. Thus, all of

the contaminants which are contained within the waste material have an affinity for the non-solvent based layer (upper phase) and only a small portion of the non-solvent based contaminants may spill over ((due to the impreciseness of the sight glass separation technique) into the solvent based layer.

5 Schmidt et al. then teaches the use of simple cartridge type filters to remove the non-solvent based contaminants (if any) from the solvent-based layer. There is no mention in Schmidt et al. of treating a solvent based layer that has contaminants which have an affinity for the solvent based layer (e.g. are dissolved or emulsified in the solvent based layer). Contaminants which have an affinity for the non-solvent based
10 layer can be readily removed by any kind of filtration technique including a cartridge filter. Schmidt et al. does not teach or suggest a process of treating a solvent based layer with contaminants which have an affinity for the solvent based layer and which can not be removed by a cartridge filter as demonstrated in conclusive test results in the previously submitted declaration of the Applicant and of record herein.

15 As noted in column 4, beginning at line 22, the lower phase is not filtered to remove any remaining traces of oils or other contaminants. The only oils or other contaminants mentioned are ones that have an affinity for the non-solvent based layer because they were separated into the non-solvent based layer by the sight glass separation technique. The only (if any) contaminants which find their way into the
20 solvent based layer are not those which have an affinity for the solvent based layer but rather are contaminants which have an affinity for the non-solvent based layer which spilled over due to the imprecise nature of the sight glass separation technique.

5 This is the only reasonable interpretation of the Schmidt et al. patent. The interpretation offered by the Examiner fails for two reasons. First, the oils and contaminants referred to at column 4, line 22 must be read in conjunction with column 3, line 64 to column 4, line 21. If such a reading is made, the only conclusion that can result is what has been described above (i.e. the Schmidt et al. solvent based layer may contain small amounts of contaminants having an affinity for the non-solvent based layer) and not the interpretation offered by the Examiner. Second, assuming arguendo that Schmidt et al. could reasonably be interpreted to describe solvent-based contaminants, the explanation offered for their removal from the solvent based layer is incomplete and would not lead one of ordinary skill in the art to the claimed invention. 10 This is because the presence of solvent based contaminants in a solvent based layer presents unique problems which are addressed in the present application and which can not be removed by cartridge filters as demonstrated in the test results shown in Applicant's declaration. No such disclosure is found in Schmidt et al. Schmidt et al. is merely referring to the removal of non-solvent based contaminants in the solvent based 15 layer (very small amounts thereof) which is a relatively simple process that can be carried out by any suitable filtration technique.


20 The process disclosed in Schmidt et al. would not remove all particulate and oily type contaminants as asserted by the Examiner at the top of page 7 of the current Office Action. The inability of the reference process to effectively remove solvent based contaminants from the solvent based layer has clearly been established in the previously submitted declaration of the Applicant.

Finally, the Examiner comments on the bottom of page 9 that the arguments presented by Applicant are not persuasive because they are based on new matter which is unsupported by the originally filed specification. As we have clearly shown, the position taken by the Examiner is unfounded and clearly does not take into consideration what is fairly disclosed in the specification and claims as originally filed and what would be clearly understood by those of ordinary skill in the art.

In view of the foregoing, Applicant submits that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due, however, if any fee is due it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,


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